



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/630,355

07/30/2003

Carsten Momma

117163.00077

9258

21324

7590

06/09/2006

HAHN LOESER & PARKS, LLP

One GOJO Plaza

Suite 300

AKRON, OH 44311-1076

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,355

Applicant(s)

MOMMA ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-29 is/are pending in the application.
- 4a) Of the above claim(s) 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/06 has been entered.

Claim Objections

Claims 3-5,7,8,10,12,14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims all depend from a canceled claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5-13,26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (6254632). Wu et al. disclose (Fig. 2B) a stent having a base body with a

Art Unit: 3738

plurality (col. 8, lines 50-56) of microdevices **200** that project from the implant surface to form a microcannula **218** on the outer surface to engage the vessel wall, col. 6, lines 13-17. The examiner is interpreting the claimed elements "penetrate into the media of the blood vessel" in this way: since the protrusions or "microcannulae" of Wu's device engage the vessel wall and secure the stent body in place, it can be construed as penetrating the wall. Additionally, any portion of the blood vessel can be construed as the "media". Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Wu also discloses the diameter and length of the microcannulae can be 100µm for both dimensions, col. 11, lines 63-66. Fig. 4A shows a cover layer **420** of biodegradable material (col. 6, lines 33-42) that closes the active substance **410** in the deposit. The microdevices are fully capable of being applied using hybrid technology. Wu additionally discloses the active substance is liberated once the stent is implanted and the microcannulae engage the vessel wall, col. 6, lines 18-26. Wu discloses the stent can be made from a biodegradable material and from a magnesium alloy, col. 4, lines 43,44,47,48,54.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. '632. Wu et al. is explained supra. Wu does disclose the lengths or depths of the

Art Unit: 3738

microcannulae can be any dimension depending on the amount of drug desires to be delivered, col. 6, lines 61-66. However, Wu fails to disclose the lengths of the microcannulae to be 180 μ m-250 μ m. It would have been an obvious matter of design choice to modify the length of the microcannulae, since applicant has not disclosed that using a length of 150 μ m or 180 μ m provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the length taught by Wu et al. or the claimed lengths in claim(s) 3,4 because both stents perform the same function of delivering a therapeutic substance to a vessel and anchoring the stent in the wall.

Claims 14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. '632 in view of Hossainy et al. (6287628). Wu et al. is explained supra. However, Wu fails to disclose the use of a biodegradable drug carrier to hold the active substance. Hossainy et al. teach that impregnated polymers can be used to hold therapeutic materials to place in the microcannulae (col. 9, lines 21-25) and that biodegradable carriers can be used, col. 10, lines 50-52, 57-59. It would have been obvious to one of ordinary skill in the art to use a biodegradable carrier to hold the drug and fill the microcannulae as taught by Hossainy in the stent of Wu et al. such that it degrades over time and has a controlled release rate at the implantation site.

Response to Arguments

Applicant's arguments filed 3/29/06 have been fully considered but they are not persuasive. In response to applicant's argument that the "microcannulae structure" of Wu's device do not penetrate the vessel wall is a misinterpretation of the reference. Clearly one of ordinary skill in the art would understand that if the stent device is secured in place or engages the vessel wall, it must penetrate the wall or "media". Since the claims do not define clearly what is meant by the "media" it can be broadly said that Wu's device clearly penetrates the media of the blood vessel. Applicant also argues that the distance of the projection of Wu's device forming the microcannula is measured from a different reference point. However, it should be noted that the claim recites the microcannula projects from the implant surface. The Examiner interprets the microcannula length from the bottom surface of the depressions in the implant to the top of the protrusion. The claims do not define where this surface is that the "microcannula" length is measured from and thus the Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. In response to Applicant's argument that Wu's device does not penetrate the media is not persuasive since no structural difference between the claimed invention and the prior art has been established in order to patentably distinguish the claimed invention from the prior art. The Examiner is entitled to give terms (i.e. media) in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be

Art Unit: 3738

subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. If the prior art structure is capable of performing the intended use, then it meets the claim. Wu's projections clearly can penetrate "media" and no special definition is being given to this term in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E. Pellegrino